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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,867	01/29/2004	Damon H. DeHart	ABB-126-A	4117

48980 7590 04/23/2009
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EXAMINER

NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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04/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@youngbasile.com
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Office Action Summary	Application No. 10/767,867	Applicant(s) DEHART, DAMON H.	
	Examiner TUAN V. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 32-41, 54, 55, 59, 60 and 63-69 is/are pending in the application.
- 4a) Of the above claim(s) 32-41, 54, 55, 59 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 63-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/7/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In the Office action mailed out on October 16, 2008, claims 1-10, 32-41, 54-55, 59-60 and 63-67 were pending in this present application. Claims 32-41, 54, 55, 59 and 60 have been withdrawn and Claims 1-10 and 63-67 were examined and rejected.
2. This Office action is in response to the Amendment filed on 1/30/09.

Response to Amendment

3. According to the amendment, claims 68 and 69 are new. Accordingly, claims 1-10, 32-41, 54-55, 59-60 and 63-69 are pending in this present application. Claims 32-41, 54, 55, 59 and 60 have been withdrawn and claims 1-10 and 63-69 are presented for examination.
4. With respect to Applicant's argument that Humphrey fails to disclose the lancet having a unitary member with two sharp tips has been fully considered but they are persuasive. Humphrey discloses the invention related to hypodermic needle and lancets (col. 2, lines 29-34). Further, Humphrey discloses the device is a hypodermic lancet (40) (col. 7, lines 45-46) that is used for piercing skin (102) and subcutaneous tissue (104) (see Fig. 3) (see col. 8, lines 41-44), thus, Humphrey discloses a lancet and a function of a lancet. Further, Figure 12 of Humphrey's drawings discloses the hypodermic lancet includes two sharp tips.

5. With respect to the limitation of "rigid unitary member". "rigid" by definition is stiff, the hypodermic lancet (40) of Humphrey penetrated skin (102) and subcutaneous tissue (140) (see Fig. 3) without bending or yielding, thus Humphrey disclose the limitation. "unitary member", by definition "of or relating to a unit" the hypodermic lancet of Humphrey is a unit.
6. With respect to the argument that The needle of Ayres was designed to penetrated the rubber stopper of a Vacutainer as a matter of fact, the configuration of the needle tip of Ayres, as shown in Figures 2, 4, and 8, would inhibit blood flow and likely be more painful to the patient have been fully considered but they are not persuasive. Examiner did not relied on Figures 2, 4, and 8 as alleged by the applicant in the rejection. Examiner was relied on the disclosure as shown in Fig. 1 in the rejection. The design of the needle tip as shown in Fig. 1 can be used as a hypodermic lancet for penetration of skin and subcutaneous tissue. Extrinsic evidence, Humphrey (US 5,607,401) discloses a hypodermic lancet having two sharp tip is for penetration of skin and subcutaneous tissue (see Figure 3, col. 7, lines 45-46 and col. 8, lines 41-44).
7. With respect to the argument that Boothroyd is non-analogous art even in light of KSR. Examiner respectfully traverses applicant's remark. The teachings as disclosed by Boothroyd encompass not only for hypodermic needle and hypodermic lancet but it can be applied to many products that have large production. It is old and well known that automation assembly results in low cost larger quantity as compare to a manual assembly, thus, one of ordinary skill in the

art would applied the teachings of Boothroyd into his/her device to reduce the manufacturing cost of his/her device.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1-10 and 63-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Humphrey (U.S. 5,607,401).**
10. Referring to claims 1-6 and 63-66, Humphrey discloses (Figs. 12 and 58) a hypodermic cylindrical needle 10 (Fig. 12) attached to a syringe (Fig. 58), that is capable to use as a lancet device, comprising: a seamless unitary member which is hollowed along at least a portion of its length wherein the needle including first and second ends wherein the first end further includes a first and second sharpened tips that are created by a pair of bevel faces or planar faces (col. 10, lines 48-54 and col. 12, lines 63-64). With respect to the limitation that the holder is configured to move the lancet to penetrate the skin of a patient, noting that the syringe and needle, is held and moved by a healthcare provider or a user to penetrate a patient skin, thus, Humphrey discloses the hypodermic needle is configured to move to penetrate the skin of a patient.

11. Referring to claim 3, the limitation of “first and second ground surfaces which at least partially define first and second sharpened tips” is product-by-process claims. Referring to claim 64, the limitation of “the first tip and the second tip are at least partially defined by first and second ground surfaces” is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.
12. Referring to claims 7-10, Humphrey discloses (Fig. 12) the needle point includes a first ground surface and a second ground surface, wherein the first ground surface and second ground surface mirror one another about the horizontal plane and each ground surface extends approximately 180 degrees about the longitudinal axis (col. 10, lines 50-52). Figure 12 appears to show the single angle ground surface and each of the ground surface extends from the horizontal plane at an acute angle relative to the longitudinal axis.
13. Referring to claim 67, Humphrey discloses the needle for penetrating patient skin, thus, Humphrey inherently discloses the needle is rigid.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. **Claims 1-10 and 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres (U.S. 3,906,932) in view of .**

17. Referring to claims 1-6 and 63-66, Ayres discloses (see Figs. 1-5 and 7) a cylindrical needle 10 and holder 22 (Fig. 5), that is capable to use as a lancet device, comprising: a seamless unitary member which is hollowed along at least a portion of its length wherein the needle including first and second ends wherein the first end further includes a first and second sharpened tips 16, 18 that are created by a pair of bevel faces 12 or planar faces and a Vacutainer tube 22

(Background of The Invention) or holder 22 (see col. 2, lines 18-65). With respect to the limitation that the holder is configured to move the lancet to penetrate the skin of a patient, noting that the Vacutainer tube 22 (Background of The Invention and Fig. 5), which also includes the needle, is held and moved by a healthcare provider or a user to penetrate a patient skin to withdraw blood sample

(Background of the invention), thus, the needle is moved by Vacutainer tube 22 or holder 22. Thus, Ayres inherently discloses the holder 22 is configured to move the needle or lancet to penetrate the skin of a patient. Ayres fails to explicitly disclose the both ends needle of the needle 40 having the same needle point design as shown in Figure 1. Noting that Ayres discloses the needle 40 is a double ended needle, one end for penetration of a septum of a Vacutainer and the opposite end for penetration of a blood vessel. However, Boothroyd discloses (Geoffrey Boothroyd, Peter Dewhurst, Winston Knight, Product Design for Manufacture and Assembly, 1994, Marcel Dekker, Inc., pages 64 and 165) that for ease of handling an assembly component during an assembly process the assembly components should be designed to have end-to-end symmetrical. It would have been obvious to one of ordinary skill in the art to provide both ends of the needle 40, as disclosed by Ayres, having the same needle point design as shown in Figure1 so that it too would have the same advantage.

18. Referring to claim 3, the limitation of “first and second ground surfaces which at least partially define first and second sharpened tips” is product-by-process claims. Referring to claim 64, the limitation of “the first tip and the second tip are at least

partially defined by first and second ground surfaces” is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.

19. Referring to claims 7-10, Ayres discloses (Fig. 7) the first ground surface 12 and second ground surface 14 is a single angle ground surface and each of the ground surface extends from the horizontal plane at an acute angle relative to the longitudinal axis. Figures 3 and 7 show the first and second ground surfaces 12, 14 mirror one another about the horizontal plane and each ground surface extends approximately 180 degrees about the longitudinal axis.
20. Referring to claims 67-69, Ayres discloses the needle for penetrating rubber stopper of the holder 22 (Fig. 5 and col. 2, lines 18-30), thus, Ayres inherently discloses the needle is rigid.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **TUAN V. NGUYEN** whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/18/09